K081579

510(k) Summary of Safety and Effectiveness

Manufacture Name:	Inventus Co., Ltd.
Contact Name:	Jeong-Nam Kim
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Contact:	Jeong-Kim Nam
Title:	General Manager
Date:	May 19, 2008

Device Proprietary Name:	Inventus Implant System
Device Common or Usual Name:	Dental Implant System
Classification Name:	Endosseous Dental Implants
Classification Code	DZE, NHA
Classification Panel	Dental Products
Regulation Number	872.3640, 872.3630

Predicate Device:

Substantial equivalence is claimed to the following devices as related to intended use and design characteristics:

- The Maestro™ System, BioHorizons Implant Systems, Inc., K010458
- US System, Osstem Implant Co., Ltd., K062030

Description of the Device

The Inventus Implant System consists of a series of root-form endosseous dental fixtures (implants) and accessories designed to support single or multiple restorations.

The implants and abutments are manufactured from titanium, conforming to ASTM F67, and the screws are manufactured from titanium alloy, conforming to ASTM F136. The implants are available in Φ3.3mm, Φ3.75mm, Φ4.0mm, Φ5.0mm, Φ5.5mm and Φ6.0mm diameters and vary in length from 9.0mm to 18.3mm. For optimal osseointegration, the implant surfaces are treated with resorbable blast media (RBM) incorporating hydroxylapatite (HA) powder.

Intended Use of the Device

The Inventus Implant System is a series of titanium endosseous dental implants and accessories for surgical implantation in the upper and/or lower jaw. It is intended to artificially provide a root structure to support prosthetics devices, such as artificial teeth, in order to restore the chewing function of the patient.

Substantial Equivalence

The Inventus Implant System is similar to other legally marketed devices based on the intended use, design, technology, material composition and performance.

Conclusion

Based on the information provided in this 510(k) premarket notification, the Inventus Implant System is substantially equivalent in terms of safety and effectiveness to the predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Inventus Company, Limited
C/o Ms. Roshana Ahmed
Senior Regulatory Affairs Associate
Canreg, Incorporated
4 Innovation Drive
Dundas, Ontario
CANADA L9H 7P3

SEP 17 2008

Re: K081579
Trade/Device Name: Inventus Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: August 26, 2008
Received: August 26, 2008

Dear Ms. Ahmed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number:

Device Name: Inventus Implant System

Indication for Use: The Inventus Implant System is a series of titanium endosseous dental implants and accessories for surgical implantation in the upper and/or lower jaw. It is intended to artificially provide a root structure to support prosthetic devices, such as artificial teeth, in order to restore the chewing function of the patient.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Device Evaluation

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